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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/656,409	09/06/2000	Scott S. Campbell	19603/1656	9516

7590 09/30/2004

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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT PAPER NUMBER

3738

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/656,409	Applicant(s) CAMPBELL ET AL. <i>cd</i>	
	Examiner William H. Matthews (Howie)	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6-4-04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The declaration under 37 CFR 1.132 filed 6-10-04 is insufficient to overcome the rejection of claims 53-57 based upon lack of a specific and substantial utility or well established utility under 35 U.S.C 101 and 35 U.S.C 112 first paragraph as set forth in the last Office action because: it refer(s) only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the objective evidence of the declaration is commensurate in scope with the claims. See MPEP § 716. Furthermore, the declaration fails to set forth factual evidence to overcome the rejections under 35 U.S.C. 101 and 35 U.S.C 112 first paragraph. In addition, the statement in paragraph 4 of the declaration is not related to the basis of the rejections presented by the Examiner. The grounds for lacking a well established utility are based upon the claimed subject matter: resetting a human circadian clock by exposing non-ocular regions, but not ocular regions to non-solar photic stimulation.

2. With regard to rejections of Czeisler et al. '212 and the Czeisler et al. journal article, Applicant contends that Czeisler et al. lacks disclosure of the limitation "exposing a non-ocular region, but not a substantially ocular region of a human subject to a non-solar photic stimulation during one or more circadian cycles". The Examiner disagrees with Applicant because figure 39b (of '212) and the use of ceiling mounted lights (journal article) anticipates the language of at least independent claim 53. The limitation

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described above and in view of the specification does not distinctly define the limitation to not include some ocular region exposure to non-solar light. In figure 39b the region exposed to light may be considered a non-ocular region and not a substantially ocular region. With regard to the journal article, Czeisler discloses the step of blindfolding.

3. With regard to Vreman et al. '275 Applicant contends that Vreman et al. '275 does not qualify as prior art. Examiner disagrees because claims 53-57 include the limitation "but not a substantially ocular region" which is not disclosed in the provisional application 60/046,188 which Applicant apparently relies upon to pre-date Vreman et al. '275.

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 53-57 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 53-57 are directed to a method of resetting a human circadian clock by exposing a non-ocular region, but not a substantially ocular region to non-solar photic stimulation. "Absence of Circadian Phase Resetting in response to Bright Light Behind the Knees" by Wright Jr. and Czeisler (Science Magazine 297 (5581):571) discloses a specific attempt to replicate the current invention without success. More specifically, Wright et al. discloses multiple attempts to reset a human circadian clock by exposing

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non-ocular regions to light. Furthermore, Wright et al. discloses ocular exposure to light is required for resetting the circadian clock. Additionally, "Setting the Human Clock: Technique Challenged" by Barinaga discloses multiple persons of ordinary skill in the art skeptical of the credibility of Applicant's claims and proposing different reasons for resetting of circadian clocks in Applicant's studies such as regression to the mean and a dimly lighted room.

Claims 53-57 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 53-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Czeisler et al. US PN 5,304,212.

Regarding claims 53-57, Czeisler et al. discloses a system comprising a temperature measuring system (lines 30-54 of column 13) and non-solar photic stimulation generating system (lines 20-65 of column 62) that activates upon an assessed time to adjust the circadian cycle of a human. Line 59 of column 39 to line 9

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of column 40, figure 11, and figure 15b describe various times when light exposure begins. The assessed time of the minimum body temperature is shown in figure 11 as ECP_{min} . Regarding claims 54-57, figure 11 shows the time of exposure occurring between about 6 hours before to 6 hours after the assessed time, ECP_{min} . Lines 6-8 of column 40 further describe a second pulse of 3500-6000 lux light beginning five hours after the initial pulse.

With regard to the positioning of the non-solar photic stimulation device, Figure 39B and lines 54 of col. 64 through line 25 of col. 65 disclose positioning such that non-ocular regions are exposed.

5. Claims 53,54,56 are rejected under 35 U.S.C. 102(b) as being anticipated by Czeisler et al. "Suppression of Melatonin Secretion in some Blind Patients by Exposure to Bright Light" (New England Journal of Medicine, Vol. 332:6-11 January 5, 1995).

Czeisler et al. discloses a method of resetting a human circadian clock by exposing non-ocular regions with non-solar light. A temperature measuring system is disclosed to assess the minimum temperature and exposure times were at 22-23 hrs after the initial temperature minimum, which would also be before the subsequent assessed minimum.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 53-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vreman et al. US PN 6,350,275 in view of Czeisler et al. US PN 5,304,212.

Vreman et al. discloses in figures 3,4, and 7 and lines 39 of col. 5 through line 13 of col. 6 a method of resetting human circadian clocks by exposing non-ocular regions with non-solar photic stimulation. Vreman et al. lacks the express written disclosure of utilizing a temperature measuring system to apply light about six hours before or after the assessed time. Czeisler et al. teaches in line 59 of col. 39 to line 9 of col. 40, figure 11, and figure 15b that it is well known to use temperature measuring systems to apply light according to an assessed time related to temperature minimums in order to reset the circadian clock. The assessed time of the minimum body temperature is shown in figure 11 as ECP_{min} . Regarding claims 54-57, figure 11 shows the time of exposure occurring between about 6 hours before to 6 hours after the assessed time, ECP_{min} . Lines 6-8 of column 40 further describe a second pulse of 3500-6000 lux light beginning five hours after the initial pulse.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the device disclosed by Vreman et al. by including a temperature measuring system to apply light about six hours before or after the assessed time, as taught by Czeisler et al. in order to reset the circadian clock of a human.

8. Claims 55 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Czeisler et al. "Suppression of Melatonin Secretion in some Blind Patients by

Exposure to Bright Light" (New England Journal of Medicine, Vol. 332:6-11 January 5, 1995).as applied to claims 53, 54, and 56 above, and in further view of Czeisler et al. US PN 5,304,212.

Czeisler et al. "Suppression of Melatonin Secretion in some Blind Patients by Exposure to Bright Light" discloses a method of resetting human circadian clocks by exposing non-ocular regions with non-solar photic stimulation dependent upon a temperature measuring system which determines minimum temperature, but Czeisler et al. "Suppression of Melatonin Secretion in some Blind Patients by Exposure to Bright Light" lacks the express written disclosure of applying light about six hours before or after the assessed time. Czeisler et al. '212 teaches in line 59 of col. 39 to line 9 of col. 40, figure 11, and figure 15b that it is well known to apply light according to an assessed time related to temperature minimums in order to reset the circadian clock. The assessed time of the minimum body temperature is shown in figure 11 as ECP_{min} . Regarding claims 54-57, figure 11 shows the time of exposure occurring between about 6 hours before to 6 hours after the assessed time, ECP_{min} . Lines 6-8 of column 40 further describe a second pulse of 3500-6000 lux light beginning five hours after the initial pulse.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the device disclosed by Czeisler et al. "Suppression of Melatonin Secretion in some Blind Patients by Exposure to Bright Light" by applying light about six hours before or after the assessed time, as taught by Czeisler et al. '212 in order to reset the circadian clock of a human.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 703-305-0316. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

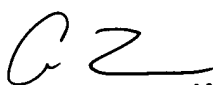
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



WHM

September 27, 2004



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